



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

005712

FEB 11 1987

MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Review of developmental toxicity study submitted  
in response to data call-in for p-chlorophenoxyacetic  
acid

TO: Geraldine Werdig, Head, PM 50  
Data Call-In Team  
Registration Division TS-767

FROM: Margaret L. Jones *M. L. Jones 2/10/87*  
Review Section III  
Toxicology Branch  
Hazard Evaluation Division TS-769

THROUGH: Marcia Van Gemert, Ph.D., Head *M. Van Gemert 2/11/87*  
Review Section III

and Theodore M. Farber, Ph.D., Chief  
Toxicology Branch *Th. Farber 2/11/87*

Compound: 4-CPA, p-chlorophenoxyacetic acid Tox. Chem: 204

Record No.: 186907 Tox. Project No.: 7-0322

Petitioner: Del Monte Corporation

Accession No.: 257347

Action Requested: Review the developmental toxicity study  
submitted in response to the data call-in for 4-CPA.

Conclusion: The submitted study is unacceptable for the  
reasons given in the attached Data Evaluation Report. The  
study cannot therefore be used to support the registration of  
4-CPA and cannot be used to support the low volume/minor use  
data waiver request.

Recommendations: The study should be repeated following the  
guidance outlined in the Pesticide Assessment Guidelines:  
Subpart F, October, 1982.

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Reviewed by: Margaret L. Jones *M. L. Jones 2/11/87*  
Section III, Tox. Branch (TS-769C)  
Secondary reviewer: Marcia Van Gemert, Ph.D.  
Section III, Tox. Branch (TS-769C)

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DATA EVALUATION REPORT

STUDY TYPE: Developmental toxicity/rabbits TOX. CHEM. NO.: 204

ACCESSION NUMBER: 257347 MRID NO.:

TEST MATERIAL: p-chlorophenoxyacetic acid

SYNONYMS: 4-CPA

STUDY NUMBER(S): BSL4054

SPONSOR: Chun King Corp., 5020 Roosevelt St., Duluth, Minn 55801

TESTING FACILITY: Biological Science Lab, Foster D. Snell, Inc.  
1509 Jarrett Pl., Bronx, N.Y. 10461

TITLE OF REPORT: A Study of the Effect of p-chlorophenoxyacetic  
acid on teratogenicity in the rabbit

AUTHOR(S): Robert A. Turner, Ph.D.

REPORT ISSUED: June 2, 1965

CONCLUSIONS: This study does not fulfill the guideline  
requirements for a developmental toxicity study for the  
following reasons:

1. Number of animals: 5 pregnant rabbits per dose were used, rather than 12, as specified in the Pesticide Assessment Guidelines, Subpart F, October, 1982.
2. Purity/batch number of the test substance were not given.
3. Age of the animals at the start of the study was not given.
4. The rationale for dose selection was not stated in the report.
5. Apparently no randomization scheme was used in assigning animals to dose groups.
6. Rabbits were dosed on gestation day 8 through 16 rather than day 6 through 18, as is normal in a rabbit developmental toxicity study.
7. The rabbits were given a "complete diet" the details of which were not specified.

8. Parental control animals were not weighed and animals were not weighed weekly.
9. Toxic signs, if any, were not recorded.
10. No toxicity was demonstrated at the highest dose tested.
11. Statistical analysis was apparently not performed.

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Classification: core-~~unacceptable~~

*Invalid mg*

Special Review Criteria (40 CFR 154.7)

A. MATERIALS:

1. Test compound: p-chlorophenoxyacetic acid, Description: none given, Batch #: not given, Purity: not given, contaminants: not given
2. Test animals: Species: albino rabbit, Strain: not given, Age: not given, Weight: At 8 weeks: parental controls were not weighed at any time during the study; mean group weights: low dose: 3.946 g., mid dose: 4.063 g., high dose: 4.007 g. Source: not given

B. STUDY DESIGN:

1. Animal assignment

Animals were assigned to the following test groups in an unspecified manner:

Test Group	Dose in diet (mg/kg)	Days 8-16 pregnant females
1 Cont.	0	5
2 Low (LDT)	5	5
3 Mid (MDT)	10	5
4 High(HDT)	25	5

Test substance was administered by capsule on gestation days 8-16.

2. Animals received a "complete diet". Details of the diet were not found in the test report.
3. Statistics were not performed.
4. Quality assurance was not performed.

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**END**